

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

UROGEN PHARMA LTD., and
UROGEN PHARMA, INC.,

Plaintiffs,

v.

TEVA PHARMACEUTICALS, INC.
and TEVA PHARMACEUTICALS
USA, INC.,

Defendants.

Civil Action No. 24-417-JFM

ANDA CASE

PLAINTIFFS' ANSWER TO DEFENDANTS' COUNTERCLAIMS

Plaintiffs/Counterclaim-Defendants UroGen Pharma Ltd. and UroGen Pharma, Inc. (collectively, “Plaintiffs” or “UroGen”) hereby respond to the numbered paragraphs of the July 10, 2024 counterclaims (D.I. 16 at 16-21) (“Counterclaims”) of Defendants/Counterclaim-Plaintiffs Teva Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. (collectively, “Defendants” or “Teva”)¹ as follows:

¹ Plaintiffs and Defendants stipulated to the dismissal of all claims against Teva Pharmaceutical Industries Ltd. (“Teva Ltd.”), without prejudice, pursuant to Fed. R. Civ. P. 41(a)(1). *See* D.I. 10. The case caption has been amended to remove Teva Ltd. accordingly. *See id.* at ¶ 16.

GENERAL DENIAL

Any allegation in Defendants' Counterclaims not expressly admitted by Plaintiffs is hereby denied. Plaintiffs deny that Defendants are entitled to the relief requested in Defendants' Prayer for Relief or to any relief whatsoever.

NATURE OF THE COUNTERCLAIMS²

1. Plaintiffs admit that Defendants' Counterclaims purport to include claims for declaratory judgment that U.S. Patent Nos. 9,040,074 (the "'074 patent") and 9,950,069 (the "'069 patent") (collectively, the "Patents-in-Suit") are invalid. Plaintiffs deny any remaining allegations in Paragraph No. 1.

THE PARTIES

- 2. Admitted.
- 3. Admitted.
- 4. Admitted.
- 5. Admitted.

JURISDICTION AND VENUE

6. Paragraph No. 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Plaintiffs deny the allegations in Paragraph No. 6.

² This Answer reproduces the headings of Defendant's Counterclaims for convenience only. This reproduction of the headings should not be construed as an admission of any of the allegations in the Counterclaims.

7. Paragraph No. 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Plaintiffs admit that this Court has subject matter jurisdiction over this action based on 28 U.S.C. §§ 1331, 1338(a), and 2201.

8. Paragraph No. 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Plaintiffs admit they are subject to personal jurisdiction in this District for the purposes of this action only.

9. Paragraph No. 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Plaintiffs admit that venue in this District is proper for the purposes of this action only.

FACTUAL BACKGROUND

10. Admitted.

11. Admitted.

12. Admitted.

13. Admitted.

14. Paragraph No. 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Plaintiffs admit that Defendants submitted Abbreviated New Drug Application (“ANDA”) No. 218215 to the United States Food and Drug Administration (“FDA”) seeking approval for the commercial manufacture, use, offer for sale, sale, or importation of mitomycin

pyelocalyceal solution, 40 mg/vial (“Teva’s Proposed ANDA Product”), prior to the expiration of the Patents-in-Suit. Plaintiffs deny any remaining allegations in Paragraph No. 14.

15. Paragraph No. 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Plaintiffs admit that Defendants submitted certifications in ANDA No. 218215 alleging that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Teva’s Proposed ANDA Product. Plaintiffs deny any remaining allegations in Paragraph No. 15.

16. Paragraph No. 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Plaintiffs admit that by a letter dated February 20, 2024 (“Teva Notice Letter”), Defendants notified Plaintiffs that Defendants filed ANDA No. 218215 containing certifications alleging that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Teva’s Proposed ANDA Product. Plaintiffs deny any remaining allegations in Paragraph No. 16.

17. Admitted.

**COUNT I: DECLARATORY JUDGMENT OF INVALIDITY OF THE ’074
PATENT**

18. Plaintiffs repeat and re-allege their answers to each of the preceding paragraphs 1-17, as if fully set forth herein.

19. Paragraph No. 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Plaintiffs admit that Plaintiffs allege Defendants committed an act of infringement by submitting ANDA No. 218215 seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Proposed ANDA Product throughout the United States prior to the expiration of the '074 patent. Plaintiffs further admit that Plaintiffs allege Defendants' commercial manufacture, use, sale, and/or importation of Teva's Proposed ANDA Product throughout the United States prior to the expiration of the '074 patent will infringe one or more claims of the '074 patent. Plaintiffs deny any remaining allegations in Paragraph No. 19.

20. Denied.

21. Paragraph No. 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Plaintiffs admit that there exists a case or controversy between Defendants and Plaintiffs related to Defendants' Counterclaims. Plaintiffs deny any remaining allegations in Paragraph No. 21.

22. Denied.

23. Denied.

**COUNT II: DECLARATORY JUDGMENT OF INVALIDITY OF THE '069
PATENT**

24. Plaintiffs repeat and re-allege their answers to each of the preceding paragraphs 1-23, as if fully set forth herein.

25. Paragraph No. 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Plaintiffs admit that Plaintiffs allege Defendants committed an act of infringement by submitting ANDA No. 218215 seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's Proposed ANDA Product throughout the United States prior to the expiration of the '069 patent. Plaintiffs further admit that Plaintiffs allege Defendants' commercial manufacture, use, sale, and/or importation of Teva's Proposed ANDA Product throughout the United States prior to the expiration of the '069 patent will infringe one or more claims of the '069 patent. Plaintiffs deny any remaining allegations in Paragraph No. 25.

26. Denied.

27. Paragraph No. 27 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Plaintiffs admit that there exists a case or controversy between Defendants and Plaintiffs related to Defendants' Counterclaims. Plaintiffs deny any remaining allegations in Paragraph No. 27.

28. Denied.

29. Denied.

PRAYER FOR RELIEF

Plaintiffs deny that Defendants are entitled to any relief, either as prayed for in the Counterclaims or otherwise.

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